I. REMARKS

The Office Action dated August 5, 2008, has been received and carefully noted. The following remarks are submitted as a full and complete response thereto.

No amendments to the specification or claims are made at this time,.

Claims 1 and 3-26 are pending, and claims 19-26 are withdrawn.

Double Patenting Rejection

Claims 1, 3-15, 17, and 18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claims 1-3, 5-11, 13-15, 17, 21, 23, and 36-38 of copending application no. 10/507,368, in view of Yuasa et al. (Yuasa et al., "Application of Calcium Silicate for Medicinal Preparation. I. Solid Preparation Adsorbing an Oily Medicine to Calcium Silicate," Chem. Pharm. Bull., 42(11), pp. 2327-2331 (1994)).

Because co-pending U.S. Patent Application No. 10/507,368 has not issued or been allowed as of the filing of this paper, filing a Terminal Disclaimer to obviate a provisional double-patenting rejection is premature. Withdrawal of the provisional double patenting rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

1. *Morein et al. and Yuasa et al.*

Claims 1 and 3-16 are rejected under 35 U.S.C. §103(a) over Morein et al. (WO 03/080029) in view of Yuasa et al. Applicants traverse the rejection.

Applicants submit that Morein et al. should be disqualified as a reference under 35 U.S.C. § 103(c), because "the subject matter [of the reference] and the claimed invention

were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person." Applicants submit that Morein et al. lists Astrazeneca AB and Astrazeneca UK Limited as Applicants. Applicants submit that although the present application currently lists NicOx SA as the assignee, the PCT application to which the present application claims priority, PCT/SE2004/001017, which was filed on June 23, 2004, lists Astrazeneca UK Limited as the Applicant. Applicants note that the PCT was later assigned from Astrazeneca UK Limited to the present assignee, NicOx SA, on October 11, 2004. However, Applicants submit that at the time the claimed invention was made, both Morein et al. and PCT/SE2004/001017 were owned by the same applicant, Astrazeneca UK Limited. Please refer to the enclosed documentation. Applicants respectfully request removal of Morein et al. as a reference in the rejection.

Applicants submit that Yuasa et al. does not teach or suggest the presently claimed invention. Applicants note that the Examiner has cited Yuasa et al. merely as a secondary reference to fulfill the deficiencies of Morein et al. As Applicants believe that Morein et al. should be removed as a reference, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-16, 18, and 19 under 35 U.S.C. § 103(a) over Morein et al. and Yuasa et al.

2. *Morein et al., Yuasa et al., and Geller et al.*

Claims 1 and 3-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morein et al. and Yuasa et al., as applied to claims 1, 3-16, 18 and 19 above, and

further in view of Geller et al. (U.S. Patent No. 5,283,067). Applicants traverse the rejection.

As stated above, Applicants assert that Morein et al. should be removed as a reference. Applicants note that the Examiner has cited Yuasa et al. and Geller et al. merely as secondary references to fulfill the deficiencies of Morein et al.

As Applicants believe that Morein et al. should be removed as a reference, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 3-19 under 35 U.S.C. § 103(a) over Morein et al., Yuasa et al., and Geller et al.

3. *Geller et al. and Del Soldato et al.*

Claims 1, 3-7, 9-13, 16 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Geller et al., in view of Del Soldato et al. (U.S. Patent No. 5,861,426). Applicants traverse the rejection.

Claim 1 of the present invention is directed to a "drug delivery composition comprising 2-[2-(nitrooxy)ethoxy]ethyl {2-[(2,6-dichlorophenyl)amino]phenyl}acetate in melted form absorbed/adsorbed onto/into particles, wherein the particles comprise materials selected from the group consisting of mannitol and lactose, optionally in admixture with one or more substances selected from the group consisting of microcrystalline cellulose, cellulose and starch" (emphasis added). Claims 3-7, 9-13, 16, and 18 depend from independent claim 1.

Applicants submit that Geller et al. and Del Soldato et al. do not teach or suggest the presently claimed invention. Applicants submit that Geller et al. discloses dry formulations suitable for the preparation of a stable, aqueous suspension for the

parenteral administration of a diclofenac salt (abstract). Applicants submit that the disclosed dry formulations are prepared by suspending the diclofenac salt in a suspending medium optionally containing pharmaceutically acceptable adjuvants such as mannitol, and removing the solvent (see col. 3, lines 15-19). Therefore, Applicants submit that there is no absorption or adsorption of drug to the adjuvant, because the drug is always in a solid form in all steps of the preparation of the formulation. In other words, Applicants submit that Geller et al. does not teach or suggest a "drug delivery composition comprising [a drug]... in melted form absorbed/adsorbed onto/into particles..." (claim 1).

Further, Applicants submit that Geller et al. discloses the use of mannitol as an adjuvant, to obtain the isotonic condition of the suspensions to be injected, and therefore, mannitol is used to obtain the same concentration of solutes (equal osmotic pressure) as blood (see col. 2, lines 41-48). In addition, Applicants submit that in the compositions disclosed in Geller et al., there is no "functional" interaction between mannitol and diclofenac salt which would modify the properties of the active principle.

Applicants submit that Del Soldato et al. does not fulfill the deficiencies of Geller et al., as Del Soldato et al. does not disclose a compound in melted form absorbed/adsorbed to a particle.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-7, 9-13, 16 and 18 under 35 U.S.C. § 103(a) over Geller et al. and Del Soldato et al.

4. *Geller et al., Del Soldato et al., and Patel et al.*

Claims 1, 3-7 and 9-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Geller et al. and Del Soldato et al. as applied to claims 1, 3-7, 9-13, 16 and 18 above, and further in view of Patel et al. (U.S. Patent No. 6,248,363). Applicants traverse the rejection.

Independent claim 1 has been discussed above. Claims 3-7 and 9-18 depend from independent claim 1.

Geller et al. and Del Soldato et al. and their deficiencies have been discussed above. Applicants submit that Patel et al. does not fulfill the deficiencies of Geller et al. and Del Soldato et al. Applicants submit that Patel et al. generally discloses pharmaceutical compositions comprising an active ingredient (abstract), wherein among the many possible active ingredients is diclofenac (col. 5, line 38). Applicants submit that Patel et al, like the other cited references, fails to disclose a composition having a drug in melted form, absorbed/adsorbed onto/into particles.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-7 and 9-18 under 35 U.S.C. § 103(a) over Geller et al., Del Soldato et al., and Patel et al.

5. *Geller et al., Del Soldato et al., Miller et al. nad Nokhodchi et al.*

Claims 1, 3-13, 16 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Geller et al. and Del Soldato et al., as applied to claims 1,3-7, 9-13, 16 and 18 above, and further in view of Miller et al. (U.S. Patent No. 5,763,452) and Nokhodchi et al. (Nokhodchi et al., "The effect of various surfactants on the release rate

of propranolol hydrochloride from hydroxyproprylmethylcellulose (HPMC)- Eudragit matrices," Eur J Pharm Biopharm, 54 (2002), pp.349-356). Applicants traverse the rejection.

Independent claim 1 has been discussed above. Claims 3-13, 16, and 18 depend from independent claim 1.

Geller et al. and Del Soldato et al. and their deficiencies have been discussed above. Applicants submit that Miller et al. and Nokhodchi et al. do not fulfill the deficiencies of Geller et al. and Del Soldato et al. Applicants submit that Miller et al. merely generally discloses pharmaceutical compositions comprising non-steroidal antiinflammatory drugs, such as diclofenac, and inert excipients such as lactose (col. 7, lines 55-65). Further, Applicants submit that Nokhodchi et al. merely discusses surfactants and their effect on the release rate of propranolol hydrochloride (abstract).

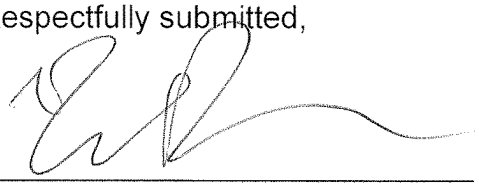
For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 3-13, 16 and 18 under 35 U.S.C. § 103(a) over Geller et al., Del Soldato et al., Miller et al., and Nokhodchi et al.

II. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event that this paper is not considered to be timely filed, an appropriate extension of time is requested. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Deposit Account No. **01-2300**, referencing Attorney Docket Number **026220.00071**.

Respectfully submitted,



Yelee Y. Kim
Registration Number 60,088

Customer Number 004372
ARENT FOX LLP
1050 Connecticut Avenue, NW, Suite 400
Washington, DC 20036-5339
Telephone: 202-857-6000
Fax: 202-857-6395

Enclosure: Pages relating to PCT/SE2004/001017